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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
1614	12

DATE MAILED: 08/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/869,333	Applicant(s) PAMPARANA, FRANCO	
	Examiner Raymond J. Henley III	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

CLAIMS 12-29 ARE PRESENTED FOR EXAMINATION

Applicant's Response/Amendment filed July 25, 2003 has been received and entered into the application. Accordingly, claims 1-11 have been canceled and claims 12-29 have been amended.

In view of such amendments, the claim objections and claim rejections under 35 U.S.C. §101/112, second paragraph, and, respecting only claims 12-26, 35 U.S.C. § 112, First Paragraph, as set forth in the previous Office action dated February 26, 2003 are withdrawn.

Claim Rejection - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-29 remain rejected under 35 U.S.C. 112, first paragraph, for the reasons of record as set forth in the previous Office action dated February 26, 2003 at pages 4-7.

Applicant's arguments at pages 5-6 have been carefully considered, but fail to persuade the Examiner of error in his determination that while the specification is enabling for preventing mortality or sudden death caused by the reoccurrence of a myocardial infarction (present specification at page 2, lines 11-15) in patients who have suffered a myocardial infarction, does not reasonably provide enablement for preventing mortality or sudden death in patients who have suffered a myocardial infarction. Claim 27 is directed to a method for preventing sudden death in a patient who is a survivor of myocardial infarction which involves the administration of the claim designated fatty acids. However, as previously expressed by the Examiner, such would

encompass death and/or mortality events which may or may not be preventable, e.g., due to Alzheimer's disease or otherwise be due to natural causes other than a reoccurrence of a myocardial infarction. Further, claims 27-29 would encompass the prevention of sudden death caused by accidents such as being hit by a car or lightning in a patient who is a survivor of a myocardial infarction. The specification simply does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant has pointed to the present specification bridging pages 3 and 4 where clinical data is set forth. The Examiner has considered this, but does not find it probative of enablement of the scope of the subject matter claimed. It merely reports that there was a 20% decrease in overall mortality, but does not state the reasons for such mortality. Also, it is stated that there was "a decrease of about 40% of mortality due to sudden death and a notable reduction in mortality due to ***other*** cardiovascular events"(emphasis added). Such implies that the cause of death was caused by a cardiovascular event.

Even more compelling to the Examiner in maintaining this rejection, is applicant's own statement at page 8 of the response (pertaining to the rejection under 35 U.S.C. 103), second paragraph that reads "No mention is made of *providing a prophylactic against mortality in the event of further infarctions,* ***which is an object of the present invention***"(emphasis added).

For the reasons of record and those above, the Examiner maintains that claims 27-29 are properly rejected.

Claim Rejection - 35 USC § 103

Claims 12-29 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Leaf et al. (U.S. Patent No. 5,760,081) in view of Derwent Abstract 1992-085863 (Nippon Oils & Fats Co. Ltd., hereinafter referred to as "Nippon"), the former reference having been made of record

by the Examiner (see form PTO-892 signed on March 13, 2002) and the latter being supplied by applicant (IDS filed November 15, 2001, reference "AO"), each reference already of record, for the reasons of record as set forth in the previous Office action dated July 25, 2003 at pages 7-9.

Applicant's arguments at pages 6-9 have been carefully considered, but fail to persuade the Examiner of error in his determination of obviousness.

Firstly, at page 7 of the response, applicant has argued that Leaf only discloses how EPA and DHA may be obtained or isolated. However, as previous set forth by the Examiner). At column 1, line 18, it is highlighted that ventricular fibrillation can lead to sudden death. At column 1, lines 21-24, it is highlighted that the high incidence of recurrent ventricular fibrillation and sudden death in survivors of cardiac arrest underscores the need for an effective approach to prophylactic treatment in these patients. At column 5, lines 21-22, the patentees teach the use of ethyl esters of EPA and/or DHA for the above purposes. It is maintained that when each of the cited portions of Leaf are considered, it fairly teaches the subject matter set forth by the Examiner.

Secondly, applicant has argued that Leaf does not teach the ethyl esters. In response thereto, the Examiner quotes Leaf at column 5, line 21 "EPA and DHA, as well as the ethyl esters...". Accordingly, applicant's position is not well taken.

Applicant has also argued that Leaf and Nippon are both directed to methods of treating ventricular fibrillation in patient with myocardial infarction, i.e., emergency treatment or treatment while undergoing open-heart surgery. The present claims, however, do not exclude that the patient being treated is not undergoing emergency treatment or open-heart surgery. Accordingly, this point is also not well taken.

Concerning Nippon, applicant has criticized this reference on the basis of the therapeutic objective taught therein. This is not probative of non-obviousness. Nippon was relied upon by

the Examiner to show the oral bioavailability of the fatty acid ester. Applicant's argument does not refute this reason for reliance upon Nippon.

Accordingly, for the reasons above, the claims are deemed to remain properly rejected.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 703-308-4652. The examiner can normally be reached on Flex.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Raymond J. Henley III
Primary Examiner
Art Unit 1614

rjh
August 1, 2003